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Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,
v.
LORA LOHR AND MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS AMICUS CURIAE IN SUPPORT OF PETITIONER MEDTRONIC

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INTEREST OF AMICUS CURIAE

The Product Liability Advisory Council, Inc. ("PLAC") is a nonprofit corporation with 114 corporate members from a broad cross-section of American industry, and the product liability lawyers who represent them. Its corporate members include manufacturers and sellers in industries ranging from electronics to automobiles to pharmaceutical products and medical devices.[1] PLAC's purpose is to file *amicus* briefs on behalf of its members on issues that affect the law of product liability. PLAC has submitted many *amicus* briefs in state and federal courts, including this Court.

In this case, the United States Court of Appeals for the Eleventh Circuit ruled that the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act expressly preempt certain state common law tort claims involving medical devices. PLAC is well-situated to address this issue. Its members often have confronted conflicting or duplicative obligations imposed by federal regulatory agencies and by state courts in product liability cases. PLAC therefore can offer a useful perspective on why uniform national standards governing medical products are important and how layers of regulatory burdens and litigation costs can impede innovation of lifesaving technologies.[2]

SUMMARY OF ARGUMENT

In adopting the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.* ("MDA"), Congress fashioned a carefully calibrated, nationwide scheme of regulation by the Food and Drug Administration ("FDA"). The MDA was structured to protect the public from unsafe medical products *and* from barriers that excessive or conflicting state and federal burdens might erect to the availability of new, useful devices.

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[1] A list of PLAC's corporate members appears in the appendix hereto.

[2] The parties' written consent to the submission of this brief is on file with the Court.

Congress thus struck a delicate balance to avoid both overregulation and underregulation of medical devices, recognizing that either would undermine public health.

To maintain that balance, Congress explicitly barred states from imposing any requirement related to the safety or effectiveness of medical devices, which differs from or adds to the requirements applicable under the Act. 21 U.S.C. § 360k(a). Congress specifically sought to avoid overlapping layers of requirements imposed by individual states, including the unpredictable and often massive burdens inflicted through common law damage actions.

The Lohrs nonetheless contend that Section 360k(a) of the MDA preempts only requirements decreed by state statutes or regulations, and not those imposed by common law standards. This Court rejected that argument with respect to the parallel — indeed, narrower — preemption provision at issue in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992). The Public Health Cigarette Smoking Act of 1969 preempted any "requirement or prohibition . . . imposed under State law" based on smoking and health. 15 U.S.C. § 1334(b). The Court found that rulings under state tort law impose "requirements." 505 U.S. at 521. Since then, nine U.S. Courts of Appeals have concluded that the word "requirements" in Section 360k(a) means the same thing it did in *Cipollone*. The Lohrs' strained interpretations of the MDA — their suggestions that common law courts do not, in the words of Section 360k(a), "establish or continue in effect" legal rules and that the context of Section 360k confers a different meaning on "requirement" than in the Smoking Act — yield no different conclusion here.

In particular, there is no basis for the Lohrs' claim that Section 360k does not preempt any state law requirement,

including any tort law standard, that happens to cover other products in addition to medical devices. The Lohrs rely not on the language of Section 360k(a) itself, but rather on an FDA regulation stating that the statute "does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices . . . ." 21 C.F.R. § 808.1(d)(1). Section 360k nowhere excludes from preemption state requirements of "general applicability." As this Court recognized in *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992), such an exception would create "an utterly irrational loophole" because "there is little reason why state impairment of the federal scheme should be deemed acceptable so long as it is effected by the particularized application of a general statute." *Id.* at 386 (citation omitted). If the regulation were to be interpreted as the Lohrs contend, it would impermissibly conflict with the statutory mandate. *See Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-44 & n.9 (1984).

In any event, the FDA regulation does not classify common law damage actions as "requirements of general applicability." Indeed, the regulation explicitly provides that state requirements established by "court decision" may be preempted. 21 C.F.R. § 808.1(b). By contrast, when identifying "State or local requirements of general applicability," the regulation omits court decisions from the list. *Id.* § 808.1(d)(1).

The Lohrs are equally wrong in arguing that a common law action alleging violation of FDA standards does not impose requirements "in addition to or different from" those applicable under the MDA, but rather merely enforces the federal requirements. A common law tort standard predicated on violation of FDA rules would require regulated companies to

pay damages, in addition to satisfying any monetary or injunctive requirements imposed by the FDA. The damages requirement would differ from and add to the requirements in the MDA, for the MDA incorporates no private right of action and imposes no duty to compensate patients for alleged personal injuries. Moreover, Congress considered excluding from preemption state laws that replicated federal standards. *See* S. 510, 94th Cong., 1st Sess. § 704 (1975). It chose not to retain such an exclusion in the MDA.

ARGUMENT

I. THE EXPRESS LANGUAGE AND LEGISLATIVE HISTORY OF THE MEDICAL DEVICE AMENDMENTS REFLECT CONGRESS'S INTENT TO PREEMPT TORT SUITS

A. In Enacting the Medical Device Amendments, Congress Struck a Careful Balance To Ensure the Safety and Availability of Medical Devices

When enacted in 1938, the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-395, scarcely touched on regulation of medical devices. *See id.* § 351 (addressing adulterated and misbranded devices). But as technology advanced and doctors relied increasingly on medical devices, Congress recognized the need for comprehensive regulation. *See generally* S. Rep. No. 33, 94th Cong., 1st Sess. 2-7 (1975) ("Senate Report"). It therefore enacted the Medical Device Amendments of 1976.

The MDA reflects a careful balancing of the public interest in the safety and effectiveness of medical devices on the one hand, and the development and availability of medical devices on the other. As discussed below, Congress determined that preserving this balance of interests necessitated preemption of state law claims such as those raised by the Lohrs.

In the MDA, Congress prescribed detailed statutory requirements for, among other things,

- premarketing reports to the FDA, 21 U.S.C. § 360(k);
- classification of devices as Class I, II, or III, depending on the extent of regulatory controls needed for a "reasonable assurance of the safety and effectiveness of the device," 21 U.S.C. § 360c(a);
- regulatory mandates adopted by the FDA when needed to provide "reasonable assurance of [the device's] safe and effective performance," governing the construction, components, ingredients, properties, testing or labeling of the device, 21 U.S.C. § 360d(a)(2)(B);
- expanded FDA inspections of company facilities, 21 U.S.C. § 374(a); and
- reports to the FDA, 21 U.S.C. § 360i.

Congress recognized both the importance of these requirements to public health and safety and the chilling effect of excessive or conflicting burdens on a dynamic, creative industry. The Senate Report on the MDA reveals Congress's concern about the potential for overregulation to stymie innovation. The Report notes, for example:

> the testimony of a number of witnesses . . . who expressed concern about the impact of this legislation on the small manufacturer of medical devices. The concern stemmed from the importance of the small innovative manufacturer in the invention and development of new medical devices and the inability of these firms, because of limited financial resources, to sustain the high level of administrative costs demanded of a highly regulated industry. . . . The Committee is confident that the administration of this new

> law will take into account the need to preserve the small manufacturer's role in the device industry.

Senate Report at 18.

The corresponding House Report voices the same concern. It cites the views of the Study Committee that originally proposed the MDA regarding the need to protect consumers from dangerous or useless products while not impeding development of lifesaving medical devices:

> Those involved in the development, promotion, and application of medical devices generally agree that the public deserves more protection against unsafe, unproven, ineffective, and experimental medical devices. But this belief is counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in this field.

H.R. Rep. No. 853, 94th Cong., 2d Sess. 10 (1976) ("House Report"). Taking these views into consideration, the House Committee concluded that its bill accommodated both objectives and

> developed a *balanced* regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions.

Id. at 12 (emphasis supplied).

To achieve this equilibrium and avoid both underregulation and overregulation, Congress made the FDA's classification of devices as Class I, II, or III hinge on the level of regulatory controls reasonably necessary to assure safety and efficacy. *See* H.R. Rep. No. 1090, 94th Cong., 2d Sess. 55-56 (1976) ("The extent of regulation under each class to provide

reasonable assurance of safety and effectiveness varies with each class . . . ."). In other words, for each device, the FDA has a statutory responsibility to calculate the appropriate level of regulation to ensure reasonable safety and effectiveness, without prescribing requirements that could unduly hinder development of lifesaving technologies. In fashioning this regulatory structure, Congress entrusted the FDA with exclusive authority not only to impose stringent controls on medical devices, but also to refrain from imposing overly stringent controls, as needed to attain this delicate balance.

B. Congress Expressly Preempted State Efforts To Add to the FDA's Requirements

Congress recognized that, in order to preserve the lines drawn by the FDA and avoid overregulation, it was necessary to foreclose others from imposing additional or differing requirements. *See King* v. *Collagen Corp.*, 983 F.2d 1130, 1138 (1st Cir.) (Aldrich, J. and Campbell, J., concurring), *cert. denied*, 114 S. Ct. 84 (1993). Simply put, it would have made no sense to mandate that the FDA carefully calibrate the level of regulation to achieve the optimal balance for each device, but then allow each of the fifty states to double or treble the burdens on manufacturers. Indeed, the House Report on the MDA explicitly states that "if a substantial number of differing requirement[s] applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." House Report at 45.

Accordingly, Congress created no private right of action under the MDA, precluding individual litigants from interfering with the FDA's regulatory agenda. The FDA has exclusive authority to enforce the statute. 21 U.S.C. § 337(a). *See also Mendes* v. *Medtronic, Inc.*, 18 F.3d 13, 19 n.4 (1st Cir. 1994)

("Congress did not intend to create a private right of action . . . .").

More importantly, Congress included in the MDA language expressly preempting state requirements on medical devices. The MDA provides that:

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any requirement* —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis supplied). Thus, any state requirement is preempted if it (i) relates to the safety or effectiveness of a medical device; and (ii) differs from or adds to a requirement applicable under the MDA.[3] Unlike statutory schemes providing minimum federal standards that states may supplement, the MDA fixes the level of regulation for medical devices and bars states from tacking on any other requirement.

II. THE COURT MUST GIVE EFFECT TO THE MDA'S PLAIN LANGUAGE MANDATING PREEMPTION

Under the Supremacy Clause, U.S. Const. art. VI, cl. 2, the congressional power to legislate includes the power to displace

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[3] To allow the FDA to fine-tune the regulatory balance even further, Congress afforded the Agency authority under specified conditions to promulgate regulations exempting from preemption certain state requirements for medical devices. *See* 21 U.S.C. § 360k(b).

state laws that would interfere with congressional objectives or undermine the uniformity of federal law. As this Court has repeatedly emphasized, whether a federal statute exercises that power depends on Congress's intent. *Cipollone*, 505 U.S. at 516; *Hawaiian Airlines, Inc.* v. *Norris*, 114 S. Ct. 2239, 2243 (1994). Where, as here, the statute expressly mandates preemption, there can be no doubt that Congress intended to preempt state law. The question is not whether the MDA overrides state law, but to what extent. *See, e.g., Cipollone*, 505 U.S. at 545 (Scalia, J., concurring in the judgment in part and dissenting in part).

To determine the preemptive reach of the MDA, this Court must "'begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose.'" *Morales*, 509 U.S. at 383 (quoting *FMC Corp.* v. *Holliday*, 498 U.S. 52, 56 (1990)). In particular, the Court "must give effect" to the "plain language [of the preemption provision] unless there is good reason to believe Congress intended the language to have some more restrictive meaning." *Cipollone*, 505 U.S. at 521 (plurality) (citations omitted); *see also id.* at 544-56 (Scalia, J., concurring in the judgment in part and dissenting in part); *see also CSX Transp., Inc.* v. *Easterwood*, 113 S. Ct. 1732, 1737 (1993) (plain wording of statute is best evidence of congressional intent to preempt).

A. The Plain Meaning of the Term "Requirement" in the MDA Includes Requirements Imposed by State Courts

The language of Section 360k(a) barring states from imposing "any requirement" different from or in addition to those under the MDA encompasses requirements imposed by state tort law. This Court held in *Cipollone* that "requirement"

or "prohibition" included common law tort rules. 505 U.S. at 521. The federal statute at issue in *Cipollone*, the Public Health Cigarette Smoking Act of 1969 ("Smoking Act"), contained an express preemption provision similar to Section 360k(a), though it contained limitations not included in the MDA provision:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

15 U.S.C. § 1334(b).

The Court held that common law damages actions impose "requirements" and "prohibitions" subject to preemption under this provision. Any contrary approach, in the Court's view, conflicted "*both* with the plain words of the [Smoking] Act *and* with the general understanding of common law damage actions." 505 U.S. at 521 (emphasis supplied). As to the expansiveness of the Act's preemption provision, the Court held:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."

Id. (quoting *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959)). Further, elaborating on the

"general understanding of common law damages actions," the Court observed that they "are premised on the existence of a legal duty and it is difficult to say that such actions do not impose 'requirements or prohibitions.'" 505 U.S. at 522.[4]

Section 360k(a) of the MDA sweeps at least as broadly as the provision that preempted common law claims in *Cipollone*. The MDA directs that "no State or political subdivision of a State may establish or continue in effect . . . any requirement" different from or in addition to those imposed under the MDA. 21 U.S.C. § 360k(a). This Court's interpretation of "requirement" in *Cipollone*, and its delineation of the reach of the preemption provision using that term, apply equally to this case. The principal difference between Section 360k(a) and the preemption provision in the Smoking Act is purely one of style: Congress used the active voice in the MDA, and the passive voice ("no requirement . . . shall be imposed under State law") in the Smoking Act.[5] This subtlety is inconsequential. Under both provisions, the actor — the party imposing or establishing a requirement — is necessarily the State, and the medium through which it acts is necessarily state law. There is no basis in the statutory text or structure to conclude that Congress intended to make the same word, "requirement," mean different things in these parallel statutory settings.

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[4] Justices Scalia and Thomas specifically agreed with the plurality on this issue, providing a majority of six Justices. *Cipollone*, 505 U.S. at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part).

[5] The Smoking Act also contained limitations on preemption which were more restrictive than Section 360k, *i.e.*, that the requirement or prohibition be "based on smoking and health" and that it pertain to "advertising or promotion" of cigarettes.

Moreover, the "general understanding of common law damages actions" has not changed in the four years since *Cipollone* was decided. Such actions remain premised now, as they were then, on the existence of a legal duty. They continue to impose requirements. *See* Restatement (Second) of Torts § 4 (1965) ("the word 'duty' is used throughout the Restatement of this Subject to denote the fact that the actor is required to conduct himself in a particular manner"); § 402A cmt. h (seller "may be required to give adequate warning"); W. Prosser & W.P. Keeton, *Prosser and Keeton on Torts* 22 (5th ed. 1984) (tort liability is based on "a departure from the conduct required of the actor by society for the protection of others"). The contention that common law damage actions are only compensatory and not regulatory lacks any vitality after *Cipollone*.[6]

Applying *Cipollone*, nine U.S. courts of appeals have held in at least 17 opinions that Section 360k(a) preempts state common law tort suits. The Lohrs rely on one errant court of appeals decision that conflicts even with precedent in the same Circuit, *compare Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *with Anguiano* v. *E.I. DuPont De Nemours &*

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[6] In *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), the court of appeals cited the *dissenting opinion* in *Cipollone* for the proposition that damages actions are merely compensatory and impose no requirements because "manufacturers facing common law challenges retain the discretion whether to alter their product or . . . bear the cost of any lawsuits that might result from their decision." *Id.* at 1459. Reliance on that dissent signals the court of appeals' deviation from the current state of the law.

Co., Inc., 44 F.3d 806 (9th Cir. 1995), to dispute that authority.[7] Their arguments are untenable.

B. Section 360k Uses the Term "Requirement" Consistently To Include State Common Law Actions

The Lohrs first contend that the word "requirement" is used differently in the MDA, where it appears three times, than in the Smoking Act, where it appears only once. Focusing on the repetition of "requirement" in Section 360k(a), the Lohrs contend that internal consistency demands an interpretation of the term confined to statutory or regulatory mandates. Brief of Cross-Petitioners ("C-Pet. Brief") at 18-19.

The reasoning behind this claim is somewhat tortured: the word "requirement," when used in Section 360k(a) to identify the federal provisions with preemptive effect, embraces only mandates "applicable . . . under this chapter" — which necessarily are imposed by federal statute or FDA regulation. Therefore, the Lohrs assert, when applied to preempted state actions, the term must again be limited to statutory and regulatory prescriptions. The Lohrs' premise is that "requirement" must have the same meaning wherever it is used.

In fact, the meaning of "requirement" does remain constant throughout Section 360k. It is only the context that changes. A "requirement applicable" under the MDA necessarily stems

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[7] The Ninth Circuit is the *only* court of appeals to hold that Section 360k(a) does not preempt state common law claims. The court reached that conclusion in *Kennedy* only after retracting its own reasoning in *Anguiano* that, in promulgating the MDA, Congress expressly intended to preempt state tort law. *See Kennedy*, 67 F.3d at 1457 n.1. The court acknowledged that its new decision was inconsistent with the holdings of the other courts of appeals that have addressed the issue. *Id.* at 1458.

from that statute or is embodied in an FDA regulation or other Agency action under it. There is no applicable federal common law. By contrast, the preempted state or local "requirements" can derive from statutes, regulations, or common law rules. "Requirement" thus means precisely the same thing throughout Section 360k. It is defined by the existence of compulsion, not by who or what does the compelling. *See, e.g., Webster's New World College Dictionary* (3d ed. 1996) (defining "requirement" as "something obligatory or demanded").

C. State Courts Can "Establish" Requirements in Common Law Tort Actions

The Lohrs also suggest that, even if courts "impose" requirements in common law damages actions within the meaning of the Smoking Act, they do not, as a matter of ordinary parlance, "establish or continue in effect" such requirements, as the MDA provides. The Illinois Court of Appeals, cited by the Lohrs, framed the argument succinctly: "Case law is handed down, developed, or decreed, but it is not 'established or continued in effect.'" *Haudrich* v. *Howmedica, Inc.*, 642 N.E.2d 206, 210 (Ill. App. 1994), *aff'd on other grounds*, 1996 WL 19012 (Ill. Jan. 18, 1996).

This argument improperly constricts the meaning of common terms. Court opinions, like statutes and regulations, *can establish* legal requirements, as this Court itself has repeatedly recognized. *See, e.g., Coleman* v. *Thompson*, 501 U.S. 722, 739 (1991) ("We can establish a per se rule that eases the burden of inquiry on the federal courts"); *Texas State Teachers Ass'n* v. *Garland Indep. Sch. Dist.*, 489 U.S. 782, 789 (1989) ("The Court then went on to establish certain principles to guide the direction of the lower courts in setting fee awards"); *West* v. *American Telephone & Telegraph Co.*, 311 U.S. 223, 236 (1940) ("the rules of decision established by

judicial decisions of state courts are 'laws' as well as those prescribed by statute") *Pickett* v. *Foster*, 149 U.S. 505, 530 (1893) ("decisions of the supreme court of Louisiana establish a rule of property binding on the federal courts"). Congress's choice of the word "establish" in the MDA rather than "impose" does not distinguish this case from *Cipollone*.

D. The Absence of the Term "State Law" in Section 360k Does Not Limit the Preemptive Reach of the Provision

The Lohrs contended in their cross-petition — though they prudently abandon the argument in their brief — that preemption under the MDA is more limited than under the Smoking Act because Section 360k does not refer to "state law" as the Smoking Act did. Cross-Petition ("C-Pet.") at 19. This contention is meritless.

In *Cipollone*, this Court held *first* that the words "requirement and prohibition" in the Smoking Act encompassed obligations imposed through state common law damages actions. It held *second* and independently that the phrase "state law" "include[s] common law as well as statutes and regulations." 505 U.S. at 521-22. Nothing in *Cipollone* suggests that the term "state law" has some talismanic significance — that to trigger preemption, Congress must employ both that term and the word "requirements." If this precise wording were necessary, Congress could not bar common law tort suits unless it recited word-for-word that "no state or political subdivision may establish or continue in effect, *through state law*, requirements or prohibitions." To insist on such a formulaic approach is nonsensical. The only way a state *can* "establish . . . requirements" is through state law. The redundancy that the Lohrs would mandate is an artificial barrier to effectuating Congress's clear objective — to prevent states

from imposing burdens, in whatever form, that upset the regulatory balance fashioned by the FDA for each device.

E. Section 360k Preempts More Than State Requirements Specifically Targeted at Medical Devices

Echoing the maverick Ninth Circuit decision in *Kennedy*, the Lohrs further contend that Section 360k(a) does not preempt their state law claims because it does not preempt state law requirements applicable to other products as well as medical devices. This contention appears to rely on the FDA's regulation providing that the MDA "does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices . . . ." 21 C.F.R. § 808.1(d)(1).

This argument is flawed in many ways. To begin with, Section 360k nowhere refers to "requirements of general applicability." By its terms, the section bars states from establishing "with respect to a device" "*any* requirement" that adds to or differs from those imposed under the MDA. 21 U.S.C. § 360k(a). "Any" is not an ambiguous word. It does not mean "some." It certainly does not mean "of general applicability." The Lohrs have cited no decision of this Court that has ever given such a strange meaning to "any" in any context whatsoever.

Nor do the words "with respect to a device" exclude requirements that also apply to other products in addition to devices. That language says that the state requirement must cover devices, not that it must encompass *only* devices and exclude other products.

Similarly, no limitation on preemption for laws of general applicability arises from the statutory provision that the preempted requirement "relate[ ] to the safety or effectiveness

of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C § 360k(a)(2). A broad rule regarding safety that applies to a medical device as well as other products relates to the safety of that device, every bit as much as a rule that addresses the particular device and no others. In *Ingersoll-Rand Co.* v. *McClendon,* 498 U.S. 133 (1990), the Court considered whether ERISA preempted an employee's claim in a tort and contract action that he was wrongfully discharged to avoid pension liability. The preemption provision of ERISA covered any state laws that "relate to any employee benefit plan." 29 U.S.C. § 1144(a). The Court noted that, as a matter of common sense, "a state law may 'relate to' a benefit plan, and thereby be preempted, even if the law is not specifically designed to affect such plans, or the effect is only indirect." 498 U.S. at 139. *See also District of Columbia* v. *Greater Washington Bd. of Trade,* 113 S. Ct. 580, 583 (1992) ("the ordinary meaning of 'relate to' . . . [is consistent with] 'deliberately expansive' language chosen by Congress") (citing Black's Law Dictionary 1288 (6th ed. 1990)). Here, too, a general duty of care may *relate to* the safety of a medical device even if the duty is not exclusively applicable to that device alone.

This Court's opinion in *Morales* also recognizes the breadth of the term "relate to" in a preemption provision. In *Morales,* the Court noted that the "ordinary meaning of these words is a broad one — 'to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with,' Black's Law Dictionary 1158 (5th ed. 1979) — and the words thus express a broad preemptive purpose." 504 U.S. at 383. At issue in *Morales* was the provision in the Airline Deregulation Act prohibiting states from enforcing any law "relating to rates, routes or services of

any air carrier." 49 U.S.C. App. § 1305(a)(1). The Attorney General of Texas argued, as the Lohrs contend here, that only state laws specifically addressed to the airline industry were preempted. The Court found that argument specious: "Besides creating an utterly irrational loophole (there is little reason why state impairment of the federal scheme should be deemed acceptable so long as it is effected by the particularized application of a general statute), this notion similarly ignores the sweep of the 'relating to' language." 504 U.S. at 386.[8] A requirement that a manufacturer of a medical device adhere to a particular standard of care thus relates to safety whether that requirement is imposed through tort laws applicable to other products, or through regulations directed only to that particular medical device.

To the extent the FDA regulation suggests otherwise, it conflicts with the plain language of the MDA. Indeed, if the FDA regulation were so interpreted, it would misread the statute. The regulation explains that state and local requirements of general applicability, along with certain other

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[8] The Court of Appeals in *Kennedy* ignored *Morales* and *Ingersoll-Rand* and instead cited *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 115 S. Ct. 1671 (1995), to limit Section 360k. But *Travelers* is inapposite. It involved a state law that imposed a surcharge on health insurance. Because employee benefit plans purchase health insurance, the petitioner argued that the law "relate[d] to . . . employee benefit plan[s]" and was preempted under ERISA, 29 U.S.C. § 1144(a), even though the state law imposed no standards of conduct on benefit plan administrators. This Court found the connection between the state law and benefit plan tenuous and peripheral. 115 S. Ct. at 1679. By contrast, a central purpose of common law tort actions is to enforce standards of conduct regarding safety. To find that those suits "relate to" the safety of a medical device does not, by any measure, stretch that term.

requirements, are "not preempted by section 521(a) of the act [Section 360k(a)] because they are not 'requirements applicable to a device' within the meaning of" Section 360k(a). 21 C.F.R. § 808.1(d). But Section 360k(a) uses the phrase "requirement *applicable to the device*" only when describing requirements imposed under federal law. 21 U.S.C. § 360k(a)(2) (emphasis supplied). As to state requirements, the statute is, if anything, broader, providing that no state may establish or continue in effect "*with respect to* a device . . . *any* requirement." *Id.* § 360k(a) (emphasis supplied). Thus, the FDA's rationale for excusing state requirements of general applicability from preemption — that they are not "applicable to a device" — is inconsistent with the plain language of the MDA and is entitled to no deference. *See Chevron,* 467 U.S. at 843 & n.9.

Even if Section 360k could properly be construed to preclude preemption of state "requirements of general applicability," the FDA's regulation reflects that the Agency does not include common law damage actions within that category. When paraphrasing the statute, the regulation provides that "no State or political subdivision of a State may establish or continue in effect any requirement . . . (whether established by statute, ordinance, regulation, or *court decision*) . . . ." 21 C.F.R. § 808.1(b) (emphasis supplied). Conversely, when identifying various requirements of "general applicability," the regulation omits court decisions and cites only statutes and ordinances, such as the Uniform Commercial Code and general electrical codes. 21 C.F.R. § 808.1(d)(1). *See Mitchell* v. *Collagen Corp.*, 67 F.3d 1268, 1277 (7th Cir. 1995) ("Section 808.1(d), listing various state requirements that are not preempted by the statute, is noticeably silent on the matter of state tort claims when read in its entirety."); *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540, 543 n.2 (3d Cir.), *cert.*

denied, 115 S. Ct. 429 (1994) ("Significantly, the list of requirements exempted from § 360k does not include state tort or common law claims."). The regulation is thus irrelevant to the issue before the Court.[9]

F. The Remedies Provision of the MDA Does Not Suggest Any Limitation on the Preemptive Reach of Section 360k

In the face of the clear language of Section 360k, the Lohrs look elsewhere in the statute for evidence that Congress did not mean what it said in that provision. That quest is suspect. As the Court held in *CSX Transportation, Inc.*, 113 S. Ct. at 1737, "the task of statutory construction must in the first instance focus on the plain wording of the [preemption] clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *See also Cipollone*, 505 U.S. at 517 (no need to look beyond express preemption provision); *Morales*, 504 U.S. at 385 (a "general 'remedies' saving clause cannot be allowed to supersede the specific substantive pre-emption provision").

Nonetheless, the Lohrs purport to find better evidence of congressional intent in 21 U.S.C. § 360h than in Section 360k, the express preemption provision. Section 360h provides that the FDA may order a company to notify doctors, hospitals and patients of unreasonable risks of a device, as well as to repair,

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[9] Concurring in the Ninth Circuit's ruling in *Kennedy*, Judge Reinhardt opined that the reference to "court decisions" in the regulation only covered those decisions based on a rule or regulation aimed specifically at medical devices. 67 F.3d at 1461. That interpretation does as much violence to the language of the regulation as the regulation, so interpreted, does to the language of the statute. As a matter of logic as well as the limitations on the judicial function, the only means by which a state court "establish[es]" a "requirement" is through common law adjudication.

replace or refund the purchase price of such a device. 21 U.S.C. §§ 360h(a)-(b). Section 360h(d) includes a limited saving clause:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

The Lohrs contend that this provision would not be necessary if state common law remedies were preempted. This contention is curious. The Lohrs' previously addressed arguments *overstated* the limitations in Section 360k. This line of reasoning *ignores* them. For one, a manufacturer might be subject to certain state law claims — and the saving clause of Section 360h would be potentially applicable — if a state went through the statutory procedures to obtain an FDA exemption from preemption for a particular requirement. *See* 21 U.S.C. § 360k(b). Moreover, as already noted, only state requirements related to the safety and effectiveness of a device or to some other requirement in the MDA are preempted. If, for example, the FDA were to order a recall of a device, the purchasers — often hospitals and physicians — might suffer an "economic loss" of the purchase price. Commercial claims for those losses may not necessarily establish requirements related to the safety or effectiveness of the device. Section 360h merely recognizes that the MDA may not in all circumstances encroach upon remedies for such commercial losses. Indeed, the focus in Section 360h(d) on "economic loss" indicates that such commercial transactions, rather than personal injury suits like this one, were what Congress had in mind.

III. PREEMPTION OF COMMON LAW CLAIMS IS NECESSARY TO EFFECTUATE THE PURPOSE OF THE MDA

Ultimately, all the Lohrs' strained readings of the statutory text and the regulatory provisions founder because they presume Congress acted illogically. Under a reading of Section 360k in which common law damage claims survive preemption but state statutes do not, the very same claims could be preempted in one state, but not in another, based on the happenstance of whether those claims rested on a common law rule or a state statute. Specifically, in a state that has adopted a product liability statute — and at least two states had done so by the time the MDA was enacted, *see* Me. Rev. Stat. Ann. tit. xiv, § 221 (adopted 1973); S.C. Code Ann. § 15-73-10 (adopted 1962) — a claim under that statute involving a medical device would be preempted, even if the state statute merely codified preexisting common law principles. But in a state with no such statute, the same claim would survive. Given Congress's express purpose in adopting the MDA to establish national uniformity in the regulation of medical devices, this result would be perverse. It makes no sense to suggest that a state may avoid preemption by including a requirement in a broad rule of common law rather than in a statute or regulation. Congress did not intend such an anomalous result.

What Congress did intend was that, for each device, the FDA gauge the level of regulation sufficient to ensure safety, while not unduly impeding innovation. Congress included a preemption provision to prevent states from subverting that intended balance. Particularly in light of that purpose, it is unreasonable to contend that Congress was concerned with the form, rather than the content and effect, of state requirements applicable to medical devices. The burdens on manufacturers

can be equally compounded, the uniformity of federal law equally impaired, and innovation equally stifled by "different or additional" state requirements, whether they are embodied in specific regulations, general statutes, or adjudication under the common law. *See, e.g., Kemp* v. *Pfizer, Inc.*, 835 F. Supp. 1015, 1023 (E.D. Mich. 1993) (describing how the preemption provisions of the MDA serve Congress's intent to alleviate "the fear and hesitancy in developing original and ground-breaking medical devices"); *Gile*, 22 F.3d at 546 ("state tort claims run counter to the important public policy, recognized by Congress, of promoting scientific inventions"); *Brown* v. *Superior Court*, 751 P.2d 470, 479 (Cal. 1988) (subjecting drug manufacturers to strict liability may discourage research and development of beneficial products); *see also* Louis Lasagna, "The Chilling Effect of Product Liability on New Drug Development," in *The Liability Maze* 334, 335 (Peter Huber and Robert Litan, eds., 1991) (burdens of defending against product liability suits are a serious disincentive to research and development of medical devices).

Indeed, as of 1996, some makers of raw materials for medical devices, because of liability concerns, have withdrawn from the market products that device manufacturers need. *See, e.g.*, 141 Cong. Rec. S1803 (daily ed. Jan. 31, 1995) (Statement of Sen. McCain) ("The cost of defending [product liability] suits often exceeds the profits generated by the sale of materials [and therefore] some manufacturers and suppliers have begun to cease supplying their products for use in permanently implanted medical devices."). And women in the United States can no longer buy *any* intrauterine device because of potential tort liability, although these products are used safely in other countries. Peter W. Huber, *Galileo's Revenge* 157, 183-84 (1991). Plainly, the burdens of litigation dwarf the state regulatory burdens that the Lohrs admit the statute

does preempt, and the former are far more unpredictable. In carefully fashioning a regulatory balance and preempting state laws to preserve it, Congress would have been reckless to have at the same time sheltered tort liability from any limitation. It did not do so.

IV. THE MDA PREEMPTS CLAIMS BASED ON FEDERAL REGULATIONS

The court of appeals below determined that the MDA preempts state tort law claims predicated on a violation of FDA standards. *Lohr* v. *Medtronic, Inc.*, Appendix to Petition in No. 95-754, at 13a-14a. That conclusion is correct. Any other result would disrupt the regulatory balance Congress struck in the MDA.

The Lohrs contend that a common law damages suit alleging a violation of the FDA standards does not impose requirements in addition to or different from those applicable under the MDA. Rather, they argue, such a suit merely enforces FDA's standards and therefore does not run afoul of Section 360k. This argument offends the plain meaning of the statute.

Even if predicated on a violation of FDA regulations or of the Federal Food, Drug & Cosmetic Act, a common law tort suit requires a regulated company to defend and potentially to pay damages for that violation. A requirement to pay damages is "different from or in addition to" the requirements in the MDA, for the MDA incorporates no private right of action and imposes no requirement to compensate patients for personal injuries. To reverse that congressional decision, to impose on regulated companies a requirement to pay damages — in addition to whatever recalls, refunds, or penalties the FDA might order and in addition to other regulatory costs the FDA regulations might impose — would create a new regulatory

balance detrimental to the innovation of important medical technologies.[10]

In fact, Congress considered and rejected a provision that would *not* have preempted state laws "identical to the Federal requirements." Such a provision appeared in the version of the MDA initially passed by the Senate. *See* S. 510, 94th Cong., 1st Sess. § 704 (1975). Congress's decision to drop that language and instead to preempt state requirements not only "different from," but also "in addition to," the MDA's requirements is conclusive. Indeed, to have any meaning, the words "in addition to" in Section 360k(a) must cover state requirements that are *not* different from those imposed under the MDA. *See, e.g., United States Dep't of Treasury* v. *Fabe*, 113 S. Ct. 2202, 2210 n.6 (1993) (each word of statute must be given meaning); *FEC* v. *National Conservative Political Action Comm.*, 470 U.S. 480, 486 (1985) (same).

Moreover, in other statutes, where Congress has intended to leave intact state laws that replicate federal standards, it has said so explicitly. *See, e.g.*, Radiation Control for Health & Safety Act, 21 U.S.C. § 360ss (no State or political subdivision may establish or continue in effect any standard "which is not identical to the Federal Standard"); National Traffic & Motor Vehicle Safety Act, 49 U.S.C. § 30103(b) (State may only prescribe or continue in effect a standard "identical to the standard prescribed under this chapter"); Federal Boat Safety Act, 46 U.S.C. § 4306 (State may not establish a standard "that

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[10] Because damages actions do not impose requirements identical to those in the MDA, the FDA's regulation indicating that Section 360k does not preempt "state or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act," 21 C.F.R. § 808.1(d)(2), is not applicable, even assuming it were consistent with the statute.

is not identical to a regulation prescribed under section 4302 of this title"); Poison Prevention Packaging Act, 15 U.S.C. § 1476(a) (same); Consumer Product Safety Act, 15 U.S.C. § 2075(a) (same); Nutritional Labeling and Education Act, 21 U.S.C. § 343-1 (same). In formulating the MDA, Congress specifically considered and omitted such language, which would have preserved identical state requirements.

As a practical matter, ruling that Section 360k does not preempt claims alleging violation of FDA standards would defeat the purpose of the provision. Many FDA requirements are quite general. For example, if the Court recognized a noncompliance exception to preemption, plaintiffs would charge in virtually every lawsuit involving an alleged failure to warn that the product labeling was "false and misleading" in violation of the Federal Food, Drug & Cosmetic Act. 21 U.S.C. § 352(a). Similarly, a case involving alleged manufacturing or design defects would likely charge that the product was adulterated. *See* 21 U.S.C. § 351(h). A complaint alleging *per se* negligence based on the violation of such a provision might well — under the noncompliance exception — survive a motion to dismiss, necessitating discovery and resulting in numerous settlements by manufacturers to avoid the cost of litigation and the risk of liability. This would raise the cost of medical devices and undermine innovation.

If such cases were to proceed, state courts and juries determining whether a violation of FDA standards had occurred would have to interpret those FDA requirements. They would have to assess the significance of the alleged violations and determine the relationship between the federal requirement that was allegedly violated and the alleged product defect giving rise to the tort claim. If the FDA had approved the product, or passed on its substantial equivalence to existing products, its

intended uses, its safety and its effectiveness, or (as often occurs) dictated the labeling, the state court would have to second-guess the Agency's decisions. If the plaintiff's theory were that the FDA had been defrauded or tricked into its decision, the Court would have to undertake a detailed examination of the FDA's decisionmaking process and determine whether and how the alleged fraud affected it. Sanctioning such inquiries would be a prescription for costly litigation that would impair the uniformity of federal regulation, invade the domain Congress assigned exclusively to the FDA, and skew the regulatory balance the MDA attempted to implement.

The Court of Appeals for the First Circuit in *Talbott* v. *Bard*, 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed,* No. 95-1321 (U.S. Feb. 16, 1996), recognized how an exception for claims based on FDA regulations would entangle state courts in the FDA's work:

> If state tort claims were allowed to go forward, a state court would initially have to determine whether the manufacturer had complied with the MDA. If, as in this case, the plaintiff claimed that the manufacturer had defrauded the FDA, the state court would need to determine whether the FDA had in fact been defrauded and whether the FDA would have approved the device absent the fraud. Under this scheme, a device manufacturer could potentially be subject to numerous inconsistent interpretations and applications of the MDA across different states, thus undermining the MDA's goal of uniformity. Moreover, if state courts erred in their application of the MDA, they would effectively be imposing requirements "different from, or in addition to" those imposed by federal law.

Id. at 29. *See also Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir.) ("states have no authority to police [manufacturers'] compliance with the FDA's procedures"), *cert. denied,* 116 S. Ct. 67 (1995); *Reeves* v. *Acromed Corp.*, 44 F.3d 300, 307 (5th Cir.) ("Allowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress's expressly stated intent in § 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers."), *cert. denied,* 115 S. Ct. 2251 (1995).

In short, to hold that damage claims alleging a violation of FDA standards are not preempted would permit state courts to duplicate the FDA's functions, defeating the purpose of granting the Agency exclusive authority to enforce the MDA and imposing burdens beyond those the Agency mandates. That was not Congress's intent.

V. THE MDA PREEMPTS PUNITIVE DAMAGES CLAIMS

The Lohrs have not asserted a claim for punitive damages, but the decision in this case could affect the issue. If the Court determines that common law tort actions for compensatory damages are preempted, it will follow *a fortiori* that claims for punitive damages are preempted as well. If, however, any of the Lohrs' tort claims withstand preemption, the Court should, for the reasons discussed below, expressly state that it is not deciding whether punitive damages claims survive preemption.

Cipollone, as noted above, expunged any argument that the purpose of tort actions is merely compensatory and not regulatory. That argument is even weaker with respect to punitive damages awards. The primary purpose of punitive damages is to regulate conduct, not to compensate victims. Punitive damages are "private fines levied by civil juries."

Gertz v. *Robert Welch, Inc.*, 418 U.S. 323, 350 (1974). *See Smith* v. *Wade*, 461 U.S. 30, 49 (1983) ("deterrence of future egregious conduct is a primary purpose . . . of punitive damages").[11]

In using punitive damages awards to punish manufacturers of medical devices for developing defective products, states impose requirements that are different from and in addition to the MDA's nationally uniform punitive sanctions applicable to adulterated or misbranded devices. The FDA may seek from any person who violates a requirement of the MDA civil penalties of up to $15,000 per violation, and $1 million per proceeding. 21 U.S.C. § 333(f)(1)(A), (B). The FDA may also initiate a criminal prosecution when a manufacturer markets an adulterated or misbranded device. *Id.* §§331(a), 333(a). Moreover, such a device is subject, at the FDA's initiative, to seizure and forfeiture, *id.* § 334(a)(2), recall, § 360h(e)(1), or a total ban. *Id.* § 360f. A requirement in a state suit to pay punitive damages clearly differs from and adds to these punishments. Whatever conclusion the Court reaches as to preemption of tort suits involving medical devices in general, punitive damages claims clearly are preempted.

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[11] *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), does not militate against preemption of punitive damages claims. In *Silkwood*, the Court held that the Atomic Energy Act did not *impliedly* preempt state tort law, including punitive damages claims. The Court relied on congressional intent, as evidenced by the legislative history of the Atomic Energy Act, to "tolerate whatever tension there was" between exclusive federal regulation of nuclear safety and a state's award of compensatory and punitive damages based on its own tort law. *Id.* at 256. By contrast, the MDA contains an *express* preemption provision that clearly communicates Congress's intent to centralize regulation of medical devices with the FDA and not to tolerate a tension between state and federal requirements.

CONCLUSION

For all the reasons set forth above, this Court should rule in favor of Medtronic and find that Section 360k preempts all the Lohrs' claims.

Respectfully submitted,

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